



LIFE CYCLE MANAGEMENT STRATEGY (LCMS)

PHARMACEUTICAL
PRODUCT LIFE CYCLE



PATENT CLIFF



INTRODUCTION TO
LCMS



TYPES OF MAJOR
LCMS

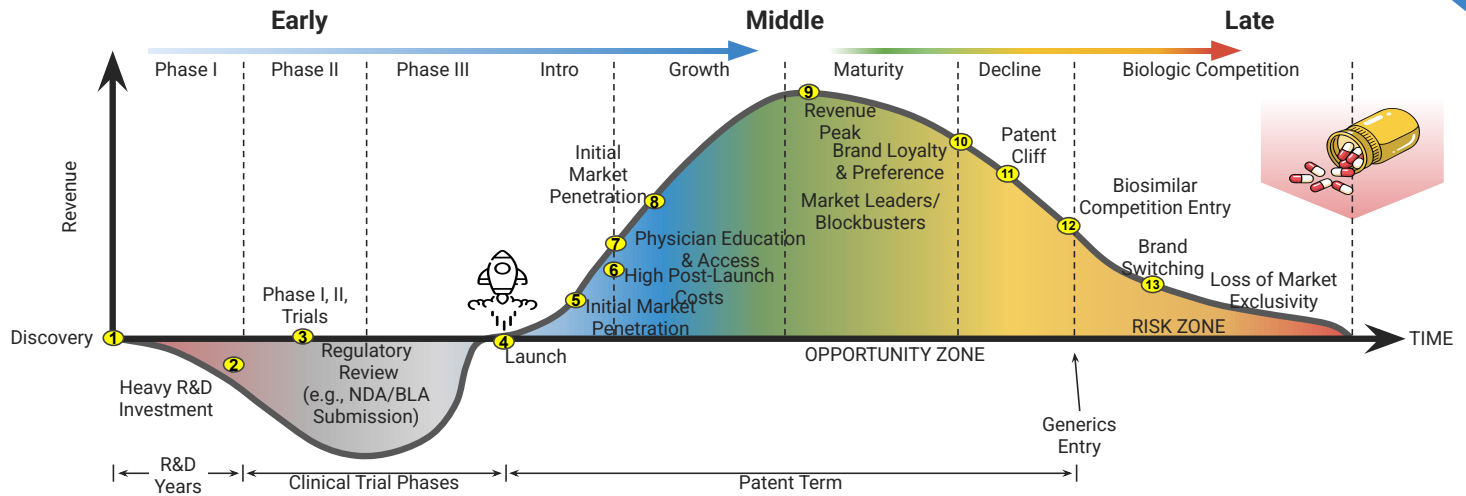


PRE VS. POST LOE
DEFENSE MECHANISM



CONCLUSION





TIMELINE FRAMEWORK

01

Early Phase (Research, Development & Approval)

This is entirely pre-revenue. The financial line dips significantly below zero, representing heavy R&D investment, capital expenditure and high clinical risk

02

Middle Phase (Market Dominance)

This represents the "Opportunity Zone" where the drug is commercialized under patent protection. Revenue grows exponentially, peaks and stabilizes

03

Late Phase (Patent Expiry and Senescence)

This is the "Risk Zone." The drug faces steep competition, and revenue falls sharply

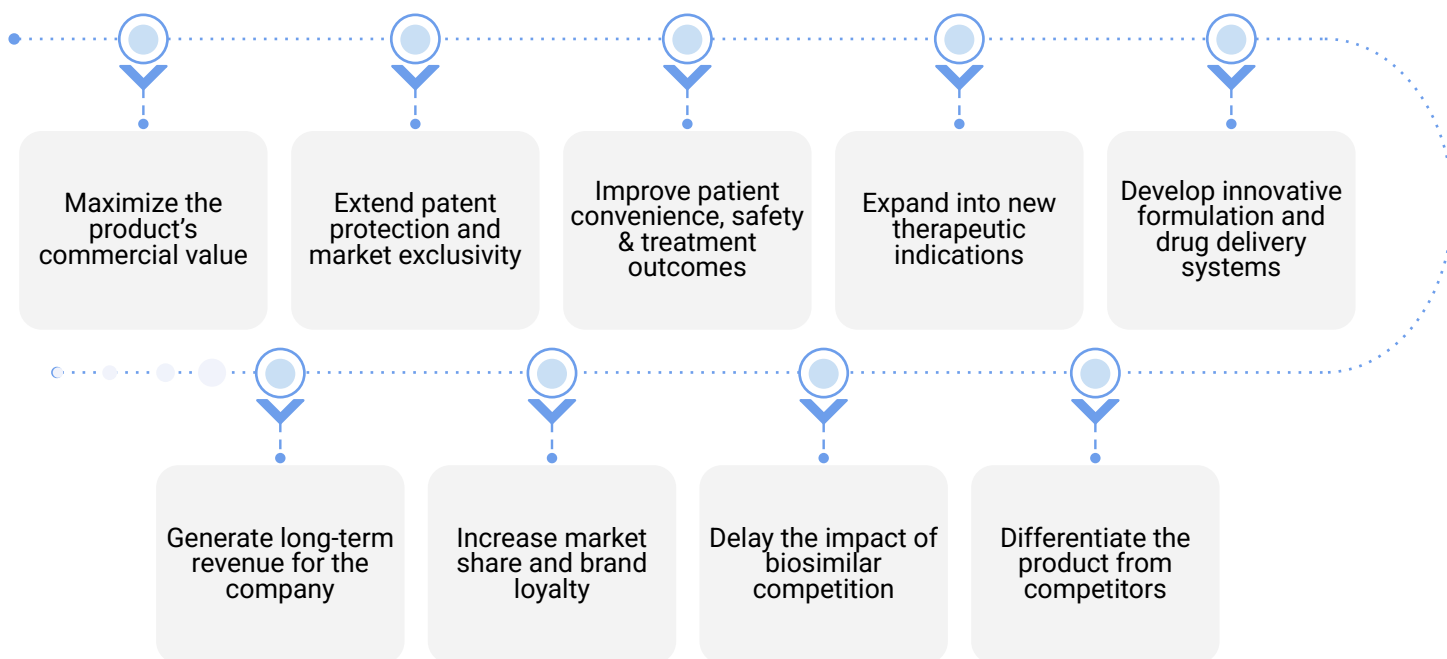
PATENT CLIFF & ITS IMPACT ON ORIGINATOR COMPANY

A patent cliff in biologics refers to the period when patents and exclusivity protections for blockbuster biologic drugs expire, allowing biosimilar manufacturers to enter the market and compete with the original product. This often causes a significant decline in revenue for the innovator company

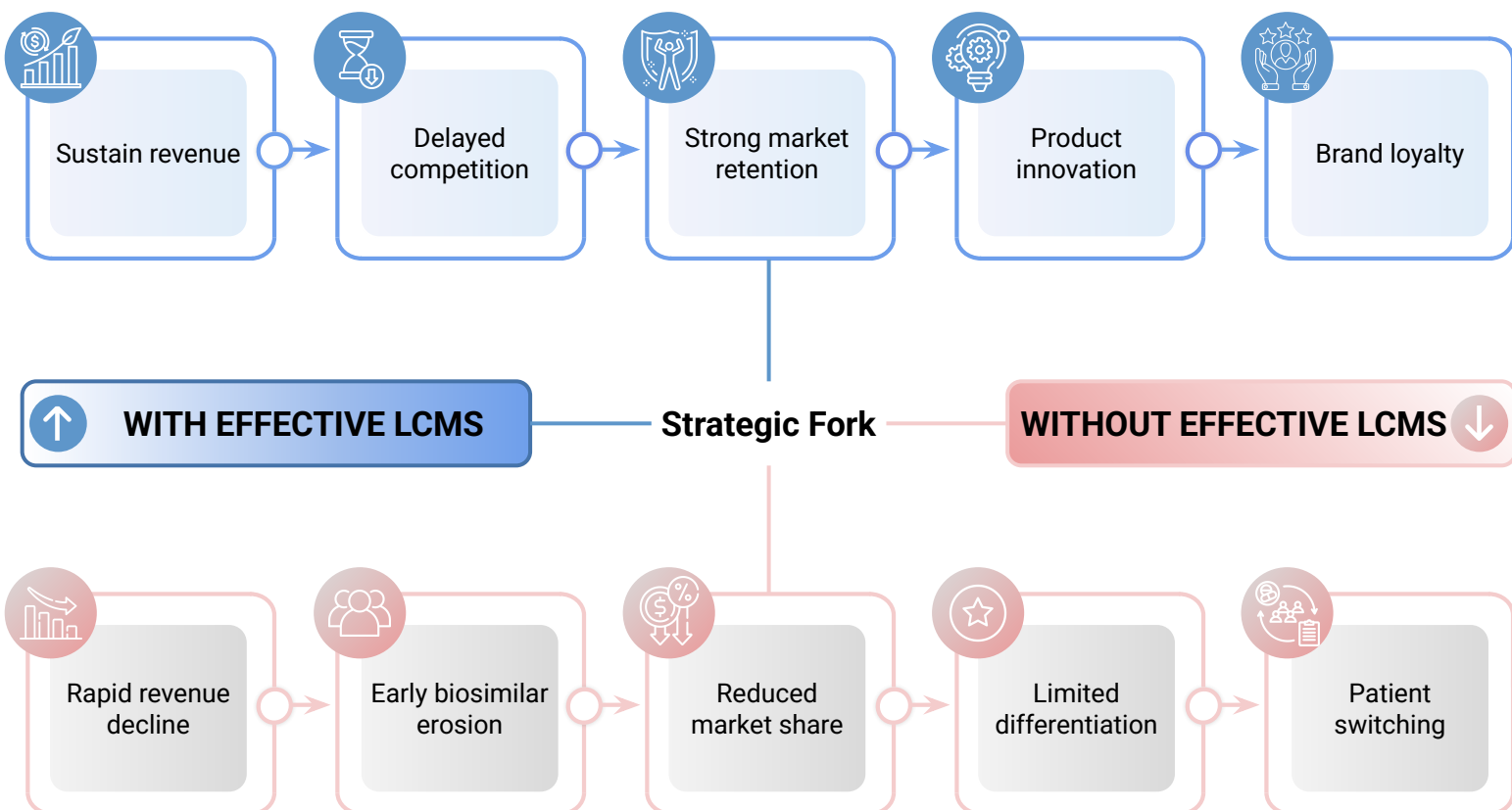
	abbvie	AMGEN	Roche	Roche
DRUG/COMPANY	Humira (adalimumab)	Enbrel (etanercept)	Avastin (bevacizumab)	Herceptin (trastuzumab)
Peak annual sales (A)	\$21.2B (2022)	\$5.4B (2018)	\$7.1B (2019)	\$7.0B (2018)
Revenue after biosimilar entry	\$4.540B (FY 2025)	\$2.200B (FY 2025)	\$1.220B (FY 2024)	\$1.340B (FY 2024)
Net revenue loss	-\$16.660B	-\$3.200B	-\$5.880B	-\$5.660B
Percentage loss	-78.58%	-59.26%	-82.81%	-80.85%
Timeline				
	2022 > FY 2025 Significant erosion by 2025	2018 > FY 2025 Moderate erosion post-LOE	2019 > FY 2024 Rapid biosimilar competition	2018 > FY 2024 Significant sales drop

Life cycle management strategy (LCMS) is a systematic approach used by pharmaceutical companies to maximize the clinical, commercial and economical value of a drug throughout its entire life cycle - from drug discovery and development to, commercialization, patent expiry and post -patent management

OBJECTIVES OF LCMS



COMPARATIVE ANALYSIS: IMPACT



LCMS Strategy	Typical Implementation Phase	EXAMPLE	Purpose
			
 Indication expansion	Mid-life cycle		Expand patient pool, enter new markets
 Reformulation Strategy	Mid-life cycle		Improve formulation characteristics
 Device innovation strategy	Late-life cycle		Improve drug delivery & administration experiences
 Next-generation strategy	Mid- to late-life cycle		Improve patient experience, new patents
 Geographical expansion strategy	Mid- to late-life cycle		Capture growth in emerging markets
 Patent thicket strategy	Late-life cycle		Delay and deter biosimilar entry
 Regulatory exclusivity strategy	Late-life cycle		Gain 6 months + 7 years of additional market exclusivity
 Patent litigation strategy	Late-life cycle		Enforce & defend intellectual property rights
 Combination therapy	Mid-Lifecycle		Enhance efficacy, create a new standard of care

Drug (Originator Company)	LCMS Strategy	Pre-LOE Defense Mechanism	Post-LOE Defense Mechanism
 MERCK KEYTRUDA	Indication expansion	Aggressively funds multi-phase clinical trials to win first-line treatment approvals for new cancer subsets	Rapidly pivots patients to a late-stage SC formulation protected by fresh formulation patents
 Roche HERCEPTIN SC	Reformulation strategy	Switches current patients over to the 2-minute subcutaneous injection format to establish a non-IV baseline	Leverages the subcutaneous delivery moat to render standard IV biosimilars commercially obsolete
 AMGEN NEULASTA ONPRO	Device innovation strategy	Bundles the biologic with a synchronized on-body injector device to build structural clinician dependency	Maintains long-term formulary position by offering a superior patient experience over standalone syringes
REGENERON EYLEA HD	Next-generation strategy	Develops a higher-dose (8 mg) formula to transition patients to a much less frequent, long-acting standard	Minimizes standard 2 mg generic/biosimilar adoption by positioning the longer dosing interval as the clinically superior option
 Johnson & Johnson DARZALEX	Geographical expansion strategy	Establishes a broad global presence and locks in early commercialization contracts across international markets	Minimizes global tender price drops by structuring separate country-specific reimbursement systems
 Roche PHESGO	Combination therapy strategy	Launches a fixed-dose combo to offer single-injection therapy and establish a preferred treatment standard	Mitigates baseline mono-therapy erosion by locking clinicians into the dual-drug regimen
 abbvie HUMIRA	Patent thicket strategy	Files dozens of overlapping formulation, dosing, and manufacturing patents to build a legal wall	Forces multi-year legal delays on rivals and negotiates staggered market entries via settlement agreements
 ALEXION SOLIRIS	Patent litigation strategy	Continually tracks, files, & updates sub-component patents to keep the drug's IP shield active	Launches aggressive patent litigation suits against biosimilar applicants to block market entry for multiple years
 AMGEN ENBREL	Regulatory exclusivity strategy	Targets highly specific, rare orphan indications to secure standalone regulatory data exclusivity periods	Blocks competitor approval applications by enforcing government-mandated, non-patent regulatory protections

CONCLUSION



- The patent cliff is inevitable, and ignoring it invites swift biosimilar erosion and up to 80%+ drops in peak annual revenue



- Formulations like subcutaneous deliveries, smart devices and fixed-dose combinations successfully insulate products by providing clear clinical superiority and patient convenience



- High-value drivers like indication expansion or combination therapies must be executed during the mid-lifecycle phase to build maximum market equity before the loss of exclusivity



- Moving forward, Life Cycle Management must be treated as a core company capability from day one of drug discovery to protect long-term commercial value and sustain funding for future breakthroughs



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